UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

December 7, 2020

Thomas Burke
Vice President of Operations
Saint Francis Hospital and
Medical Center Medical Center
114 Woodland Street
Hartford, Connecticut 06105-1299

SUBJECT: SAINT FRANCIS HOSPITAL AND MEDICAL CENTER - NRC INSPECTION NOS. (03001246/2020001) AND NOTICES OF VIOLATION

Dear Mr. Burke:

This letter refers to the safety and security inspections conducted on October 19-21, 2020 at your Hartford, Connecticut facility (Inspection Report Nos. 03001246/2020001, enclosed). This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The enclosed reports present the results of these inspections.

Based on the results of this inspection, the NRC has determined that five Severity Level IV safety violations and one Severity Level IV security violation of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notices of Violation (Notices) because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices when preparing your response. Please provide separate responses for the security and safety violations. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notices will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. However, the material enclosed herewith contains Security-Related Information as described above. Therefore, the material in the enclosures will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). To the extent possible, your

Enclosures 3 and 4 contain Sensitive Unclassified Non-Safeguards Information Upon separation, this cover letter is DECONTROLLED.

response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Robin Elliott of my staff at (610) 337-5076 or via electronic mail at robin.elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03001246
License No. 06-00854-03

Enclosures:
1. Notice of Violation Safety
2. Inspection Report No. 03001246/2020001 Safety
3. Notice of Violation Security
4. Inspection Report No. 03001246/2020001 Security

cc w/ enclosures
Greg Hisel, Radiation Safety Officer

cc w/o enclosures 3 & 4
State of Connecticut

SAINT FRANCIS HOSPITAL AND MEDICAL CENTER - NRC INSPECTION NOS. (03001246/2020001) AND NOTICES OF VIOLATION DATED DECEMBER 7, 2020

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Cover Letter\L06-00854-03.2020001.NOV safety.docx

☐ SUNSI Review		X Non-Sensitive ☐ Sensitive		X Publicly Available ☐ Non-Publicly Available	
OFFICE	RI:DNMS	RI:DNMS	RI:DNMS		
NAME	RElliott (RLE)	ETindle-Engelmann (ETE)	DJanda (DMJ)		
DATE	11/13/2020	11/13/2020	11/13/2020		

OFFICIAL RECORD COPY

NOTICE OF VIOLATION-SAFETY

Saint Francis Hospital and Medical Center
Hartford, Connecticut

Docket No. 03001246
License No. 06-00854-03

During an NRC inspection conducted on October 19-21, 2020, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. 10 CFR Part 35.2092 requires, in part, that a licensee shall maintain records of the disposal of licensed materials as required by 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

   Contrary to the above, for an undetermined period of time prior to October 20, 2020, Saint Francis Hospital and Medical Center (SFHMC) did not maintain records for the disposal of licensed materials as required by 35.92. Specifically, no waste records were maintained for Radium-223 (Ra-223) waste that was stored for decay in the Radiation Oncology department since the inception of the program.

   This is a Severity Level IV violation. (NRC Enforcement Policy, Section 6.3).

2. 10 CFR Part 35.61 requires, in part, that a licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 annually.

   Contrary to the above, SFHMC did not calibrate a survey meter used to show compliance with this part and 10 CFR Part 20 in 2019. Specifically, survey meter with serial number 6178 used for performing surveys during Yttrium-90 procedures was calibrated on February 22, 2018, and not again until February 25, 2020.

   This is a Severity Level IV violation. (NRC Enforcement Policy, Section 6.3).

3. 10 CFR Part 35.24(f) requires, in part, that licensees authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, shall establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.

   Contrary to the above, between January 2019 and October 2020, SFHMC's RSC did not include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management. Specifically, the nursing service was last represented on the RSC in the fourth quarter of 2018 and did not participate in meetings held in 2019 or 2020.

   This is a Severity Level IV violation. (NRC Enforcement Policy, Section 6.3).

4. Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 30, 2014 (ADAMS Accession No.: ML14192B052).

   The application includes a procedure for Radioactive Waste Disposal which states, in part, that on a quarterly basis, the health physicist will make an inventory of the total quantity of radioactive materials stored at SFHMC as used for Nuclear Medicine and therapeutic purposes.

   Contrary to the above, between November 2017 and October 2020, SFHMC did not, on a quarterly basis, make an inventory of the total quantity of radioactive materials stored at SFHMC as used for Nuclear Medicine and therapeutic purposes. Specifically, the health physicist did not perform the stated inventory of either the Nuclear Medicine or therapeutic wastes since the last NRC inspection in [insert month/year of last inspection].

   This is a Severity Level IV violation. (NRC Enforcement Policy, Section 6.3).

5. Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 30, 2014 (ADAMS Accession No.: ML14192B052).

   The application includes a procedure for Restricted Area Survey Procedures which states, in part, in Section B.3. that radiopharmaceutical storage and radiopharmaceutical waste storage areas, will be surveyed weekly with a radiation detection survey meter and in Section B.4. that sealed source and brachytherapy storage areas will be surveyed quarterly with a radiation measurement survey meter.

   Contrary to the above, between November 2017 and October 2020, SFHMC did not perform weekly surveys of radiopharmaceutical storage and waste storage areas with a radiation detection survey meter and did not perform quarterly surveys in sealed source and brachytherapy storage areas with a radiation measurement survey meter. Specifically, weekly surveys of the Ra-223 waste storage area were not performed and quarterly surveys of the storage areas for unused brachytherapy seeds, Carbon-14, and Strontium-90 sealed sources were not performed.

   This is a Severity Level IV violation, (NRC Enforcement Policy, Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Saint Francis Hospital and Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a

Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 7th day of December 2020

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001246/2020001
Docket No.	03001246
License No.	06-00854-03
Licensee:	Saint Francis Hospital and Medical Center 114 Woodland Street Hartford, Connecticut 06105-1299
Location(s):	Saint Francis Hospital and Medical Center 114 Woodland Street Hartford, Connecticut 06105-1299
Inspection Dates:	October 19-21, 2020 with in office review concluding November 19, 2020.

Inspector(s):

/RA/ ***12/07/20***

Robin Elliott — date
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

/RA/ ***12/07/20***

Elizabeth Tindle-Engelmann — date
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Approved By:

/RA/ ***12/07/20***

Donna Janda, Chief — date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Saint Francis Hospital and Medical Center
NRC Inspection Report No. 03001246/2020001

A routine announced safety inspection was performed at Saint Francis Hospital and Medical Center (SFHMC), on October 19-21, 2020. In office review concluded on November 19, 2020. The inspection was conducted with regard to NRC radioactive materials license number 06-00854-03; the inspection was conducted in accordance with inspection procedures 87131, 87132, 87122, and the TheraSphere and SIRSpheres Yttrium-90 Microspheres guidance. The inspection focused on the performance of the licensee's program through direct observation of work activities, interviews with licensee workers, demonstrations by workers performing licensed activities, independent measurements of radiation conditions at the licensee's facilities, and review of selected records.

During the inspection five severity level IV (SLIV) violations of NRC requirements were identified. The violations involved the failure to: 1) maintain records of Ra-223 decay in storage waste; 2) annually calibrate a survey meter used to conduct surveys of TheraSphere Y-90 procedures; 3) include a member of the Nursing service on the Radiation Safety Committee (RSC); 4) follow the Radioactive Waste Disposal policy which required a quarterly inventory of all waste in storage; and 5) follow the Restricted Area Survey policy which required weekly surveys of radiopharmaceutical waste and quarterly surveys of sealed source storage.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspectors reviewed the organization and scope of the licensee's programs through direct observation of work activities, interviews with licensee workers, and review of selected records.

b. Observations and Findings

SFHMC was a large community hospital that was authorized for 35.100, 35.200, 35.300, 35.400, 35.600 high dose rate remote afterloader (HDR), 35.1000 microspheres and a self-shielded blood irradiator. The program was supervised by a Radiation Safety Committee (RSC) which met quarterly. The Radiation Safety Officer (RSO) was a consultant physicist that was on site regularly and was supported by a full-time Assistant RSO. The RSO performed the annual program review of the radiation safety program.

The Nuclear Medicine (NM) Department consisted of three areas: general nuclear medicine, cardiology and positron emission tomography (PET). There were four cameras in general nuclear medicine, two cameras in cardiology and one camera in PET. There were two treadmills in cardiology. There was one hot lab in each nuclear medicine location. The department was staffed with five full-time nuclear medicine technologists (NMT) and one per diem NMT all of whom rotated through all three areas.

The Radiation Oncology (RO) Department was staffed with two full-time authorized medical physicists (AMP) and three locum AMPs. There were three authorized users (AU) for both 35.400 and 35.600 HDR; however, one AU worked at different location that did not have an HDR. Gynecological treatments composed the majority of the HDR oncology procedures. The unit had previously been used for bronchial, esophageal and smit sleeve procedures. Radium-223 (Ra-223) Xofigo therapies were performed in the RO department under the supervision of three AUs. A strontium-90 (Sr-90) eye applicator remained in storage. There were two AUs for Y-90 TheraSphere procedures.

The Blood Bank utilized a gamma irradiator to sterilize blood samples. It was staffed 24 hours a day, 365 days a year. A manager of the area monitored the use of the irradiator and arranged for all required maintenance.

2. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspectors reviewed the material receipt, use, transfer, and control of the licensee's programs through direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and a review of selected records.

b. Observations and Findings

Direct Observations/Interviews/Demonstrations

The inspectors toured all the NM facilities and observations included: package receipt, dose preparation, injection, scanning, patient interaction, security of licensed material, surveys and waste disposal. Interviews were conducted with the RSO, NMTs, and representatives of administration. NM performed approximately 20 procedures per day including a wide variety of general studies. Unit doses were typically used for all scheduled tests and three bulk shipments of Technicium-99m (Tc-99m) were received each day from Cardinal Health. Radionuclides used included Tc-99m, Fluorine-18, Xenon-133, Indium-111, Iodine-123, Iodine-131 (I-131), Ra-223 and Sr-90. All doses were assayed prior to administration. In 2020 to date, 35 I-131 procedures were performed requiring a written directive. The maximum I-131 dose was 200 millicuries and the licensee performed in-patient treatments.

The inspectors toured the RO department including the HDR vault and control room, and sealed source storage. Xofigo waste was stored in a cabinet in the HDR vault. Weight based doses of Xofigo were received in NM and verified prior to administration in the dose calibrator. Injection of the dose was performed in RO. There were 13 administrations of Xofigo in 2019, and 4 to date in 2020. In 2020 to date, four Y-90 TheraSphere procedures were performed. NM received the doses and verified them prior to administration in the dose calibrator. The manufacturer's checklist was completed for each treatment. Waste was stored with NM waste. Permanent brachytherapy was limited to Iodine-125 prostate treatments. In 2019, 22 patients received prostate implants and in 2020 to date, 7 implants were done. The reduction in number of implants was COVID-related. The inspector observed an AMP and AU deliver a vaginal cylinder treatment to a patient. No concerns were noted. In 2019, 26 patients received a total of 72 fractions and in 2020, to date 26 patients were treated for a total of 63 fractions. The inspectors reviewed written directives for all types of therapy studies, spot checks and calibration records. The inspectors surveyed the waste and the sealed source storage locations in the RO department.

Blood bank staff received irradiator training prior to working in the facility and completed a log when the irradiator was used. There were no incidents reported involving the irradiator since the last inspection. Emergency procedures and contact information were posted at the irradiator. A radiation survey of the facility yielded measurements consistent with the licensee postings.

Record Review

The following records were reviewed: irradiator use logs, emergency postings, maintenance logs, written directives, patient release instructions, patient release calculations, written procedures for: radioactive waste disposal and restricted area survey procedures, daily area surveys, weekly area wipes, package receipt, package return, sealed source inventories, sealed source leak tests, dosimetry, waste disposal, instrument calibration, dose calibrator calibrations, annual audits, radiation safety training, and DOT/HAZMAT training. Some records were maintained electronically, and some were maintained on paper.

The following is a summary of the findings from the records review:

- A review of the Xofigo, Ra-223 dichloride, records revealed that while waste was surveyed when it was placed in the cabinet in the HDR vault, there was no documentation kept for this survey, who performed the survey, which survey meter was used, how much waste was contained in the cabinet at any given time, or the survey of the waste prior to its disposition into the medical waste stream. 10 CFR 35.2092 requires that records of waste held for decay must be maintained and include the information stated above.

- A radiation survey meter that was used primarily for surveys conducted during TheraSphere treatments was calibrated February 22, 2018, and not again until February 25, 2020. The serial number of the survey meter was recorded on the documentation completed for survey conducted for Y-90 treatments in 2019. 10 CFR 35.61 requires that instruments used for these surveys to be calibrated annually.

- A review of the Radiation Safety Committee minutes showed that the committee had representation from the Nursing service in 2018 but the last meeting that the representative attended was in the fourth quarter of 2018. The meetings held in 2019 and 2020 did not include a representative from the Nursing service. 10 CFR 35.24 requires the meetings to include a Nursing representative.

- In a review of the licensee written policies/procedures for Radioactive Waste Disposal it was noted that the policy required the health physicist to conduct quarterly inventories of radioactive material stored as waste in both NM and Radiation Oncology. There were no inventories conducted of waste materials in RO for the period evaluated, i.e. from September 2017 to October 2020.

- In a review of the licensee's written policy for Restricted Area Survey Procedures in Section B.3. it was noted that radiopharmaceutical storage and radiopharmaceutical waste storage areas will be surveyed weekly with a radiation detection survey meter and in Section B.4. it was noted that the policy required quarterly surveys with a radiation measurement survey meter of sealed source storage areas. There were no surveys performed of the Ra-223 waste or the RO sealed source storage as required in the procedure.

<u>Independent Radiation Measurements</u>

Independent radiation surveys were conducted in the irradiator room, sealed source storage area, HDR console area during treatment, hot labs, camera rooms, injection areas and outside PET quiet rooms; the survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits.

Instrument type: Model # 2401-P
NRC S/N: 344918 calibration expiration date: December 6, 2020

Instrument type: Model # 2401-P
NRC S/N: 281353 calibration expiration date: January 30, 2021

c. Conclusions

During this inspection, five SLIV violations of NRC requirements were identified. The following are the violations:

6. 10 CFR Part 35.2092 requires, in part, that a licensee shall maintain records of the disposal of licensed materials as required by 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.
Contrary to the above, for an undetermined period of time prior to October 20, 2020, SFHMC did not maintain records for the disposal of licensed materials as required by 35.92. Specifically, no waste records were kept for Ra-223 Xofigo waste that was stored for decay in the Radiation Oncology department since the inception of the program.

   This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

7. 10 CFR Part 35.61 requires, in part, that a licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 annually.
Contrary to the above, SFHMC did not calibrate a survey meter used to show compliance with this part and 10 CFR Part 20 in 2019. Specifically, survey meter with serial number 6178 used for performing surveys during Yttrium-90 procedures was calibrated on February 22, 2018, and not again until February 25, 2020.

   This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

8. 10 CFR Part 35.24(f) requires, in part, that licensees authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, shall establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.
Contrary to the above, between January 2019 and October 2020, SFHMC's RSC did not include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management. Specifically, the nursing service was last represented on the RSC in the fourth quarter of 2018 and did not participate in meetings held in 2019 or 2020.

   This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

9. Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 30, 2014, (ADAMS Accession No.: ML14192B052).

   The application includes a procedure for Radioactive Waste Disposal which states, in part, that on a quarterly basis, the health physicist will make an inventory of the total quantity of radioactive materials stored at SFHMC as used for Nuclear Medicine and therapeutic purposes.

   Contrary to the above, between November 2017 and October 2020, SFHMC did not on a quarterly basis, make an inventory of the total quantity of radioactive materials stored at SFHMC as used for Nuclear Medicine and therapeutic purposes. Specifically, the health physicist did not perform the stated inventory of either the Nuclear Medicine or therapeutic wastes since the last inspection.

   This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

10. Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 30, 2014, (ADAMS Accession No.: ML14192B052).

    The application includes a procedure for Restricted Area Survey Procedures which states, in part, in Section B.3. that radiopharmaceutical storage and radiopharmaceutical waste storage areas, will be surveyed weekly with a radiation detection survey meter and in Section B.4. that sealed source and brachytherapy storage areas will be surveyed quarterly with a radiation measurement survey meter.

    Contrary to the above, between November 2017 and October 2020, SFHMC did not perform weekly surveys of radiopharmaceutical storage and waste storage areas with a radiation detection survey meter and did not perform quarterly surveys in sealed source and brachytherapy storage areas with a radiation measurement survey meter. Specifically, weekly surveys of the Ra-223 waste storage area were not performed and quarterly surveys of the storage areas for unused brachytherapy seeds, C-14, and Sr-90 sealed sources were not performed.

    This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3).

3. Exit Meeting

On November 19, 2020, the inspectors conducted an exit meeting by telephone with SFHMC. The inspection finding and violations were discussed. The licensee acknowledged the inspection findings and discussed corrective and preventative actions.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at entrance meeting
* Individual(s) present at on-site inspection debrief
+Individual(s) present for telephonic exit meeting

#+ Anne Bilisko, Supervisor of Nuclear Medicine
+ George Daskalov, Chief Medical Physicist
#*+ Gregory Hisel, Radiation Safety Officer
#+ Michael Reynolds, Director Radiology

INSPECTION PROCEDURES USED

IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs
IP 87122, Irradiator Programs
TheraSphere and SIRSpheres Yttrium-90 Microspheres

LIST OF ACRONYMS USED

AMP: Authorized Medical Physicist
AU: Authorized User
CFR: Code of Federal Regulations
HDR: High Dose Rate Remote After Loader
NM: Nuclear Medicine
NMT: Nuclear Medicine Technologist
NRC: Nuclear Regulatory Commission
PET: Positron Emission Tomography
RO: Radiation Oncology
RSC: Radiation Safety Committee
RSO: Radiation Safety Officer
SFHMC: Saint Francis Hospital and Medical Center
SLIV: Severity Level IV